



## Workshop on ENABLING STANDARDS FOR NANOMATERIAL CHARACTERIZATION

October 8-9, 2008

National Institute of Standards and Technology  
Gaithersburg, Maryland USA

### Final Meeting Program

Day 1

October 8, 2008

8:00 am Registration and Coffee

8:30 am Opening Remarks

Welcome

**Robert J. Celotta (Director, NIST Center for Nanoscale Science and Technology)**

Overview of Agenda and Objectives

**Vince Hackley (National Institute of Standards and Technology)**

#### SESSION 1 – OVERARCHING ISSUES AND NEEDS FOR STANDARDS

8:40 am Clinical Translation of Cancer Nanotechnology - Framework and Standardization

**Piotr Grodzinski (National Cancer Institute)**

9:00 am Standards Needs for Occupational Exposure Assessment of Nanomaterials

**Aleks Stefaniak (National Institute for Occupational Safety and Health)**

9:20 am Metrology and Standards Needs for Nanotoxicology

**Steve Hankin (Institute of Occupational Medicine - UK)**

9:40 am The Need for Verifiable Science in Assessing Nanomaterial Hazards

**Kenneth Dawson (University College Dublin - Ireland)**

10:00-10:15 am Coffee Break

#### SESSION 2 – PERSPECTIVES: INDUSTRY, ACADEMIA, AND THE REGULATORY PROCESS

10:15 am Multi-Industry Perspectives on Standards for Nanotechnology

**Michael Garner (Intel Corporation)**

10:30 am Reference Standard Needs for the Development of Nanoscale Pharmaceutical Products

**Ron Iacocca (Eli Lilly and Company)**

10:45 am Developing Useful Standards for Industry

**Joe Vasiliou (Thermo Fisher Scientific)**

11:00 am Assessing Safety and Efficacy of Nanotechnology Medical Products: An FDA Perspective

**Subhas G. Malghan (US Food and Drug Administration, Center for Device and Radiological Health)**

11:15 am Perspectives from ISO TC 229/TC24: Particle Characterization Related Projects

**Michael Stintz (University of Technology Dresden - Germany)**

11:30 am The Emerging Role of Academic Institutions in Standards Development  
**Stacey Harper (Oregon Nanoscience and Microtechnologies Institute – ONAMI, Oregon State Univ.)**

11:45 am Facilitated Discussion with Questions to Speakers  
**Moderators: James Kelly and Vince Hackley (NIST)**

12:00 – 1:00 pm Box lunch with extended discussion

### **SESSION 3 – INTERLABORATORY STUDIES AND STANDARDS DEVELOPMENT**

1:00 pm Inter-laboratory Studies (ILS) – Multi-Laboratory Participation in Standards Development  
**Tim Brooke (ASTM International)**

1:20 pm Overview and Objectives of ASTM-Sponsored Interlaboratory Studies (ILS)  
**Anil Patri (Nanotechnology Characterization Laboratory - NCI)**

1:30 pm Summary & Discussion of ILS 166 Findings on Nanoparticle Size Measurements  
**Alan Rawle (Malvern Instruments Inc. / ASTM E56.02 Co-Chair)**

2:30 pm Summary & Discussion of ILS 201 Findings for Biological Testing of Nanomaterials: Hemolysis  
**Marina Dobrovolskaia (Nanotechnology Characterization Laboratory - NCI)**

2:50 pm Summary & Discussion of ILS 202 Findings for Biological Testing of Nanomaterials: Cytotoxicity  
**Stephen Stern (Nanotechnology Characterization Laboratory - NCI)**

3:10 – 3:20 pm Coffee Break

3:20 pm Facilitated Discussion: Lessons Learned – Summary and Recommendations for Future Studies  
**Alan Rawle and Anil Patri**

6:00 pm Social/Dinner (Holiday Inn, Gaithersburg)

## **Day 2 October 9, 2008**

8:00 am Coffee

8:20 am The Path Forward – Opening Statements and Objectives for Day 2  
**Vince Hackley (NIST)**

### **SESSION 4 – NEED FOR COOPERATION AMONG TESTING LABS & STAKEHOLDERS**

8:30 am Importance of Collaboration Among Federal Agencies and SDOs in International Standards Development  
**Clayton Teague (U.S. National Nanotechnology Coordination Office)**

8:45 am NIST-NCL: Prototype for Interagency Cooperation on Measurements and Standards  
**Debra Kaiser (National Institute of Standards and Technology)**

9:00 am The NanoHealth and Safety Initiative: Maximizing Safety through Design  
**Sally Tinkle (National Institute of Environmental Health Sciences, Office of the Acting Director)**

9:15 am Nanomaterial Environmental Health and Safety: Information Needs for Decision Makers  
**Jeff Morris (Environmental Protection Agency)**

9:30 am APEC Interlaboratory Studies: Asia-Pacific Cooperation on Nanomaterial Testing  
**Åsa Jamting (National Measurement Institute – Australia)**

9:45 am Facilitated Discussion: Forming a Community of Interest  
**Moderators: Scott McNeil and Ken Dawson**

10:15-10:30 am Coffee Break

## **SESSION 5 – FACILITATING STANDARDS DEVELOPMENT AT THE PRE-STANDARDS LEVEL**

10:30 am Benefits of Pre-Standards Development and ILS by Electronic Means  
**Marty Fritts (Nanotechnology Characterization Laboratory - NCL)**

10:40 am Demonstration of Wiki Capabilities for Pre-Standards Development  
**Raul E. Cachau (NCI Frederick Biomedical Supercomputer Center)**

11:10 am Facilitated Discussions:

(1) Wiki user requirements, data curatorship and operational procedures

(2) Integrating a Community of Interest and Multiple Standards Development Organizations

**Moderators: Marty Fritts and Tim Brooke**

12:00 pm Logistics and Charge for Afternoon Breakouts  
**Jim Kelly (NIST) and Vince Hackley (NIST)**

12:10 – 1:00 pm Lunch (box lunch provided at meeting site)

1:00 pm Breakout Sessions on Prioritization & Initiation of Efforts

Session 1 – Protocol Development – Biological Interactions

**Discussion Leaders: Ken Dawson (UCD), Anil Patri (NCL), Jennifer Hall (NCL)**

Session 2 – Protocol Development – Physical Property Characterization

**Discussion Leaders: Ron Iacocca (Eli Lilly), Alan Rawle (Malvern/ASTM E56), Jeff Clogston (NCL)**

Session 3 – Reference & Test Materials, Media & Sample Preparation

**Discussion Leaders: Fred Klaessig (PBNS), Vince Hackley (NIST), Aleks Stefaniak (NIOSH)**

Session 4 – Interlaboratory Studies & forming a Community of Testing Laboratories

**Discussion Leaders: Tim Brooke (ASTM), Marty Fritts (NCL/ASTM E56), Jim Kelly (NIST)**

3:00 – 3:15 pm Coffee Break

3:15 pm Facilitated Discussion: Results and Feedback from Breakout Sessions

Request for Advocates/Chairs to Initiate Work Items

Community Organization – Call for Participants

Refining Work Items - Scheduling and Action Items

Wiki Development, Deployment

**Moderators: Marty Fritts (NCL) and Breakout Leaders**

4:15 pm Workshop Wrap-Up and Final Remarks

**Scott McNeil (Director, Nanotechnology Characterization Laboratory)**

## SPEAKER AND ORGANIZER INFORMATION

(alphabetical order)



**Timothy Brooke**

Staff Manager, Committee E56 on Nanotechnology, ASTM International, West Conshohocken PA



**Marina Dobrovolskaia, Ph.D.**

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**C. Michael Garner, Ph.D.**

Program Manager, Experimental Materials Research, Technology Strategy, Technology and Manufacturing Group, Intel Corporation, Santa Clara CA



**Prof. Kenneth Dawson, Ph.D.**

Chair of International Alliance for NanoEHS Harmonization, Director, Centre for BioNano Interactions (CBNI), School of Chemistry and Chemical Biology, University College Dublin, Ireland



**Piotr Grodzinski, Ph.D.**

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**Ronald G. Iacocca, Ph.D.**

Research Advisor, Eli Lilly & Company, Lilly Research Laboratories, Product Research and Development, Analytical Sciences Research and Development, Indianapolis IN



**Scott E. McNeil, Ph.D.**

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**Åsa Jamting, Ph.D.**

Experimental Scientist, Nanometrology Group, Physical Metrology Branch, National Measurement Institute, Lindfield, NSW Australia



**Jeff Morris, Ph.D.**

National Program Director for Nanotechnology, Office of Research and Development, U.S. Environmental Protection Agency, Washington DC



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**Michael Stintz, PD Dr.-Ing. habil.**

Head, Research Group Mechanical Process Engineering, Institute of Process Engineering and Environmental Technology, Technische Universität (University of Technology) Dresden, Germany



**Alan F. Rawle, Ph.D.**

Divisional Manager for Applications Support, Co-Chair ASTM E56.02, Malvern Instruments Inc., Westborough MA



**E. Clayton Teague, Ph.D.**

Director, National Nanotechnology Coordination Office, Committee on Technology, National Science and Technology Council, Executive Office of the President, Arlington VA



**Aleksandr Stefaniak, Ph.D., CIH**

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**Steve Stern, Ph.D.**

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**Joe Vasiliou, MSME**

Metrology Engineer, Chair ASTM E29.03, Head of U.S. Delegation for ISO TC24/SC4 on Particle Characterization, Specialty Diagnostics Group, CDX Fremont, Thermo Fisher Scientific, Fremont CA